

JUL 24 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K131690.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen,
518057, P. R. China

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Contact Person:

Yang Zhaohui

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: May 23, 2013

2. Device Name: M7/M7T Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

M7/M7T Diagnostic Ultrasound System is a general purpose, portable/mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW mode, Color-Mode, Color M-Mode, Power/Dirpower Mode, TDI mode or the combined mode (i.e. B/M-Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.5 MHz to 10.0 MHz.

4. Intended Use:

The M7/M7T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes, thyroid), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, urology, orthopedic, and musculoskeletal (conventional and superficial), intraoperative and transesophageal(cardiac) exams.

5. Comparison with Predicate Devices:

M7/M7T Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	Mindray	M7/M7T	K121010

The only difference between the subject device and the predicate device is that the Q-view software had been installed to the subject device to enable Q-path.

Q-path is a network server provided by Telexy Healthcare Inc. for digital image storage. Q-view is a client viewing tool for the server. Telexy Healthcare developed technology and a command structure that allows any Q-view enabled ultrasound system to access Q-path directly from the ultrasound system using a single control. The primary purpose for Q-view is to provide remote access to Q-path from the ultrasound system, eliminating the necessity to log in to Q-path from a separate workstation.

The subject device and the predicate device have the same technological characteristics.

and they are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes.

6. Non-clinical Tests:

M7/M7T Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, UD 3, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, ISO14971, ISO 10993-1, IEC62304 and IEC60601-2-18.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the M7/M7T Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 24, 2013

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Yang Zhaohui
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Shenzhen, Guangdong, 518057
P.R. CHINA

Re: K131690

Trade/Device Name: M7/M7T Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, and ITX
Dated: July 15, 2013
Received: July 17, 2013

Dear Yang Zhaohui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the M7/M7T Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2s	V10-4s	V10-4Bs	7L4s	L14-6s	P4-2s
P7-3s	4CD4s	6C2s	7L5s	L7-3s	L12-4s
L14-6Ns	P12-4s	CW2s	7LT4s	P7-3Ts	

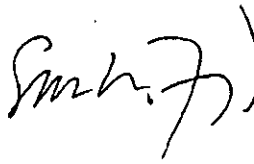
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K131690

Device Name: M7/M7T Diagnostic Ultrasound System

Indications for Use:

The M7/M7T diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes, thyroid), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, urology, orthopedic, and musculoskeletal (conventional and superficial), intraoperative and transesophageal (cardiac) exams.

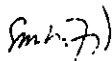
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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006_1

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

N/A

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1,2,3,4,6,7,8
	Abdominal	P	P	P	P	P	P	Note 1,2,3,4,5,6,7,8
	Intraoperative (specify)*	P	P	P		P	P	Note 1,2,4,6,7,8
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1,2,3,4,5,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2,4,6,7,8
	Neonatal Cephalic	P	P	P	P	P	P	Note 1,2,4,5,6,7,8
	Adult Cephalic	P	P	P	P	P	P	Note 1,2,4,5,6,7,8
	Trans-rectal	P	P	P		P	P	Note 1,2,4,6,7,8
	Trans-vaginal	P	P	P		P	P	Note 1,2,4,6,7,8
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	Note 1,2,4,5,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2,4,6,7,8
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7,8
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1,2,5,6,7,8
	Cardiac Pediatric	P	P	P	P	P	P	Note 1,2,5,6,7,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note 1,2,5,6,8
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

C5-2s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Abdominal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

V10-4s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-vaginal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7,8
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K 131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

V10-4Bs

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-vaginal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7,8
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes

***Other use includes urology

Note 1: Tissue Harmonic Imaging The feature does not use contrast agents.

Note 2: Smart3D; Note 3 4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

7L4s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	Note 1,2, 4,6,7,8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
Cardiac	Intravascular							
	Other (specify)***							
	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
Peripheral Vascular	Intra-Cardiac							
	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Mindray Co. Ltd.- M7/M7T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

L14-6s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	Note 1,2, 4,6,7,8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E:

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

P4-2s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

P7-3s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,8
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,8
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	Note 1, 2,5,6,8
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6,8
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health
 510(k) K 131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

4CD4s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 3, 4, 6, 8
	Abdominal	P	P	P		P	P	Note 1, 2, 3, 4, 6, 8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1, 2, 3, 4, 6, 8
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3: 4D(Real-time 3D); Note 4: iScape; Note 5: TDI

Note 6: Color M; Note 7: Biopsy Guidance; Note 8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

6C2s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Adult Cephalic	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K 131690

Mindray Co. Ltd.- M7/M7T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: 7L5s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K 131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

1.7-3s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K 131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

L12-4s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K 131690

Mindray Co. Ltd.- M7/M7T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

L14-6Ns

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

PI2-4s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,8
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,8
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6,8
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,8
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note.1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

CW2s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric				P			
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

* Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging The feature does not use contrast agents

Note 2: Smart3D. Note 3: 4D(Real-time 3D); Note 4: iScape, Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K 131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

7LT4s

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2,4,6,7,8
	Intraoperative (specify)*	P	P	P		P	P	Note 1,2,4,6,7,8
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2,4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2,4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	Note 1,2,4,6,7,8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2,4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2,4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2,4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690

Diagnostic Ultrasound Indications for Use Form

System:

M7/M7T Diagnostic Ultrasound System

Transducer:

P7-3Ts

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CW D	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note 1,2,5,6,8
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D; Note 3:4D(Real-time 3D); Note 4: iScape; Note5: TDI

Note6: Color M; Note7: Biopsy Guidance; Note8: Amplitude Doppler

(Signature)

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131690